

68-14-1. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643;
effective June 15, 1992; amended March 20, 1995; amended July 30, 1999; revoked P-_____
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68-14-2. Definitions. As used in this article of the board's regulations and the pharmacy practice act, each of the following terms shall have the meaning specified in this regulation:

(a) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

(b) "Blood component" means that part of blood separated by physical or mechanical means.

(c) "Common ownership and control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or ~~otherwise~~ by other means.

(d) "Drug sample" means a unit of a prescription-only drug that is not intended to be sold, is intended to promote the sale of the drug, and is distributed on a gratuitous basis.

(e) "Device" has the meaning specified in K.S.A. 65-656, and amendments thereto.

(f) "Emergency medical reasons" shall include transfers of prescription-only drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of these transfers shall not exceed five percent of the total prescription-only drug sales revenue of either the transferor or transferee pharmacy during any period of 12 consecutive months.

(g) "Excursion" means a deviation from the range of temperatures specified by the manufacturer for storage or transport of a prescription-only drug or device based on stability data.

(~~f~~)(h) "Intracompany sales" ~~means~~ and "intracompany distribution" mean any transaction or transfer between any division, subsidiary, parent, affiliated, or related company under the

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common ownership and control of a corporate entity.

~~(g)~~(i) "Primary owner" means any person owning or controlling more than 50 percent of the wholesaler's business.

(j) "Room temperature" means a temperature that is maintained thermostatically and meets the following requirements:

(1) Encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F);

(2) results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and

(3) allows for excursions between 15° and 30°C (59° to 86°F) experienced in facilities, such that the allowable calculated mean kinetic temperature remains in the allowed range.

(k) "Virtual wholesale distribution" means arranging for the distribution of a drug or device, which may include taking actual possession of the drug or device and shall include contracting with another entity for the distribution, purchase, and sale of the drug or device.

(l) "Virtual wholesale distributor" means a business entity that arranges for the distribution of a drug or device, with or without taking actual possession of the drug or device, and contracts with others for the distribution, purchase, and sale.

~~(h)~~(m) "Wholesale distribution" means distribution of prescription-only drugs or devices to persons other than a consumer or patient and shall include virtual wholesale distribution and virtual wholesale distributors, but this term shall not include any either of the following:

(1) Intracompany sales;

(2) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing

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organization or from other hospitals or health care entities that are members of these organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the U.S. internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) the sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives of the authorized distributor of record, in accordance with 21 U.S.C. 353; or

(8)(2) the sale, purchase, or trade of blood and blood components intended for transfusion.

(i) ~~"Wholesale distributor"~~ means anyone doing business in this state and engaging in wholesale distribution of prescription-only drugs, including the following:

(1) Manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

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~~(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;~~

~~(8) independent wholesale drug traders; and~~

~~(9) retail pharmacies that conduct wholesale distributions. (Authorized by and implementing K.S.A. 65-1630; implementing K.S.A. 65-1626, as amended by L. 2019, ch. 52, sec. 7, K.S.A. 65-1643, K.S.A. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended P-_____.)~~

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68-14-4. Minimum required information for registration. (a) Each wholesale distributor, virtual wholesale distributor, third-party logistics provider, or outsourcing facility shall provide the board with the following minimum information as part of the registration requirements described in K.S.A. 65-1645, and amendments thereto, and as part of any renewal of any registration:

- (1) The name, ~~full~~ commercial business address, and telephone number of the registrant;
- (2) each trade or business name used by the registrant;
- (3) the address, telephone number, and name of the contact person for each facility used by the registrant for the storage, handling, and distribution of prescription-only drugs or devices;
- (4) the type of ownership or operation, including partnership, corporation, or sole proprietorship; and
- (5) the name of each owner, operator, ~~or both~~ facility manager, and designated representative of the registrant, including the following:
 - (A) If a person, the name, address, and date of birth of the person;
 - (B) if a partnership, the name, address, and date of birth of each partner; and the name of the partnership;
 - (C) if a corporation, the name ~~and~~ title, address, and date of birth of each corporate officer and director, the corporate name, and the name of the state of incorporation; and
 - (D) if a sole proprietorship, the ~~full~~ name, address, and date of birth of the sole proprietor and the name of the business entity;
- (6) a list of all states where the registrant is registered as a wholesale distributor, virtual wholesale distributor, third-party logistics provider, or outsourcing facility;

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(7) a copy of any current DEA registration;

(8) all disciplinary actions or sanctions by any state or federal agency against the registrant or any principal, owner, director, officer, facility manager, or designated representative thereof;

(9) if the facility is located outside of Kansas, a record of the following:

(A) A current registration in the state where the registrant is located;

(B) a satisfactory inspection conducted within the previous 36-month period by the registering entity of the state where the registrant is located. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the registrant within the previous 36-month period by a third party recognized by the board to inspect may be accepted; and

(C) a designated resident agent in Kansas for service of process, the record of whom shall also be on file with the secretary of state; and

(10) if the registrant is an outsourcing facility, a record of the following:

(A) A current outsourcing facility registration from the food and drug administration (FDA); and

(B) a current inspection report from an FDA inspection conducted within the previous 24-month period that indicates compliance with the requirements of the federal food, drug and cosmetic act, including guidance documents and current good manufacturing practices established by the FDA. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the registrant within the previous 36-month period by a third party recognized by the board to inspect may be accepted.

(b) A single registration may be issued by the board for any business entity operating more

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~~than one facility within this state, or for a parent entity with divisions, subsidiaries, affiliate companies, or some combination of these within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities~~ Each registrant shall provide the board with a surety bond that meets the requirements of 21 U.S.C. 360eee-2.

(c) Each registrant shall provide and maintain, in readily retrievable form, a list of all manufacturers, wholesale distributors, third-party logistics providers, outsourcing facilities, and dispensers with which the registrant is transacting business.

(d) Each registrant shall submit revised information requested by subsection (a) within 30 days after any change in that information. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643, K.S.A. 65-1645 and, K.S.A. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended P-_____.)

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68-14-5. Personnel. ~~As a condition for receiving and retaining a wholesale distributor registration, the~~ (a) Each wholesale distributor registrant, virtual wholesale distributor registrant, third-party logistics registrant, or outsourcing facility registrant shall require each person employed in any ~~prescription-only drug~~ wholesale distribution, virtual wholesale distribution, third-party logistics, or outsourcing activity to have, or any combination of these activities, to receive education, training, and experience, or any combination of these, sufficient for that person to perform the assigned functions in a manner providing assurance that the drug product quality, safety, and security will at all times be maintained as required by law. Each registrant shall maintain records of the training, education, and experience for five years.

(b) Each wholesale distributor registrant, virtual wholesale distributor registrant, or third-party logistics provider registrant shall designate an individual as the facility manager, who shall be responsible for all aspects of the registrant's operation.

(c) Each outsourcing facility registrant shall designate a pharmacist-in-charge, as defined by K.S.A. 65-1626 and amendments thereto, who shall be responsible for all aspects of the registrant's operation. (Authorized by ~~and implementing~~ K.S.A. 65-1630; implementing K.S.A. ~~1998 Supp. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended P-_____.)~~

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68-14-7. Wholesale distributors; minimum requirements for the storage and handling of prescription-only drugs and devices and for the establishment and maintenance of prescription-only drug and device distribution records. Each wholesale distributor registrant shall meet the following minimum requirements for the storage and handling of prescription-only drugs and devices, and for the establishment and maintenance of prescription-only drug and device distribution records by ~~wholesale distributors~~ the registrant and ~~their~~ its officers, agents, representatives, and employees.:

(a) Facilities. Each facility at which prescription-only drugs and devices are stored, warehoused, handled, held, offered, marketed, transported from, or displayed shall meet the following requirements:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, ~~or~~ adulterated, counterfeit, or suspected of being counterfeit, or that are in immediate or sealed, secondary containers that have been opened or deemed unfit for distribution;

(4) be maintained in a clean and orderly condition; ~~and~~

(5) be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) be a commercial location and not a personal dwelling or residence;

(7) have sufficient storage space to maintain records of all transactions for at least five

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years; and

(8) be in a location separate from any other wholesale distributor or pharmacy registered by the board or another state.

(b) Security.

(1) Each facility used for wholesale ~~drug~~ distribution shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs or devices are held shall be limited to authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(4) Each registrant shall ensure adequate accountability and control of all controlled substances in compliance with the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations.

(5) Each registrant shall verify that all persons or entities who undertake, either directly or by any other arrangement, to transport prescription-only drugs or devices on behalf of the registrant ensure security.

(c) Storage. All prescription-only drugs and devices shall be stored at appropriate

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temperatures and under appropriate conditions in accordance with ~~requirements, if any, in the labeling~~ manufacturer's recommendations to preserve the stability of these drugs and devices, or with requirements in the 1995 edition of the United States pharmacopeia/national formulary (USP/NF), which is adopted by reference.

(1) If no storage requirements are established for a prescription-only drug or device, the drug or device may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these ~~methods~~ means shall be utilized to document proper storage of prescription-only drugs and devices at least once during each 24-hour period.

(3) The ~~record-keeping~~ recordkeeping requirements in subsection (f) of ~~this regulation~~ shall be followed for all stored prescription-only drugs and devices.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined ~~for identity to identify~~ and to prevent the acceptance of ~~contaminated~~ prescription-only drugs or ~~prescription-only drugs~~ devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected ~~for identity of~~ to identify the prescription-only ~~drug products~~ drugs or devices and to ensure that there is no delivery of

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prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

(3)(A) No registrant shall engage in the wholesale distribution of prescription-only drugs or devices that are purchased or received from pharmacies or practitioners or from wholesale distributors that obtained the drugs or devices from pharmacies or practitioners.

(B) Any registrant may receive for redistribution prescription-only drugs or devices returned from pharmacies or practitioners that were distributed by the registrant. Before redistribution, the registrant shall examine the prescription-only drug or device to ensure that it has not been opened or used. If the prescription-only drug or device has been opened, it shall be quarantined and physically separated from other prescription-only drugs or devices until the prescription-only drug or device is destroyed.

(C) Any registrant that also operates as a reverse logistics provider or returns processor may receive prescription-only drugs or devices for destruction from pharmacies and practitioners regardless of where the drugs or devices are obtained. Each registrant shall maintain documentation for the disposition of prescription-only drugs or devices sent for destruction with proof of destruction, including a certificate of destruction, for inventory accountability and shall maintain records documenting any return to the supplier.

(4) The ~~record-keeping~~ recordkeeping requirements in subsection (f) of this regulation shall be followed for all incoming and outgoing prescription-only drugs or devices.

(e) Returned, damaged, and outdated prescription-only drugs or devices.

(1) Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-

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only drugs and devices until they are destroyed or returned to their supplier.

(2) ~~Any~~ Each prescription-only ~~drugs~~ drug or device whose immediate or sealed outer or sealed secondary ~~containers have~~ container has been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription-only drugs or devices until ~~they are~~ the drug or device is either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, the ~~wholesale distributor~~ registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its container, carton, or labeling, as a result of storage or shipping.

(4) The ~~record-keeping~~ recordkeeping requirements in subsection (f) ~~of this regulation~~ shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs or devices.

(f) ~~Record-keeping~~ Recordkeeping.

(1) Each ~~wholesale distributor~~ registrant shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs and devices. These records shall include the following information:

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(A) The source of the drugs and devices, including the name and principal address of the seller or transferor, and the address of the location from which the drugs or devices were shipped;

(B) the identity and quantity of the drugs and devices received and either distributed or disposed of; and

(C) the dates of receipt and either distribution or other disposition of the drugs and devices.

(2) Each record related to the wholesale distribution of prescription-only drugs or devices, including invoices of purchase or sale, packing slips, and shipment records, shall accurately reflect the name of the registrant as that name appears on the registration issued by the board.

(3) Inventories and records shall be made available for inspection and photocopying by an authorized federal, state, or local law enforcement agency officials representative of the board for five years following disposition of the prescription-only drugs or devices.

~~(3)~~ (4) Records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized ~~official of a federal, state, or local law enforcement agency~~ representative of the board.

(5) Each registrant shall post all current federal and state registrations in a conspicuous place.

(g) Written policies and procedures. Each ~~wholesale distributor~~ registrant shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage,

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inventory, and distribution of prescription-only drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each ~~wholesale distributor~~ registrant shall establish, maintain, and adhere to the following written policies and procedures:

(1) A procedure by which the oldest approved stock of a prescription-only drug ~~product or device~~ is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate to meet the needs of the receiving facility;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs and devices. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) a procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency; and

(4) a procedure to ensure that ~~any~~ all outdated prescription-only drugs or devices ~~shall be~~ are segregated from other drugs or devices and either returned to the manufacturer or destroyed.

This procedure shall provide for written documentation of the disposition of outdated

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prescription-only drugs and devices. This documentation shall be maintained for five years after disposition of the outdated prescription-only drugs or devices; and

(5) a procedure to ensure that prescription-only drugs and devices are distributed only to registered entities with the authority to possess prescription-only drugs or devices in Kansas and to maintain documentation of this authority as part of the distribution record.

(h) Responsible persons. Each ~~wholesale distributor~~ registrant shall establish and maintain lists a list of officers, directors, managers, and other persons in charge of wholesale prescription-only drug and device distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the board.

(i) Compliance with federal, state, and local law.

(1) Each ~~wholesale distributor~~ registrant that deals in controlled substances shall register with the ~~drug enforcement administration~~ DEA.

(2) Each ~~wholesale distributor~~ registrant shall permit the board's authorized personnel ~~and authorized federal, state, and local law enforcement officials~~ to enter and inspect the distributor's registrant's premises and delivery vehicles; and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(3) These officials shall be required to show appropriate identification before being permitted access to wholesale distributors' premises and delivery vehicles Each registrant shall operate in accordance with the requirements of 21 U.S.C. 353, 21 U.S.C. 360eee-1, 21 U.S.C. 360eee-2, and any implementing regulation.

(j) Salvaging and reprocessing. Each ~~wholesale distributor~~ registrant shall be subject to the

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provisions of any applicable federal, state, or local laws or regulations that relate to prescription-only drug ~~product~~ or device salvaging or reprocessing. (Authorized by K.S.A. 65-1630 ~~and~~ implementing K.S.A. 65-1634 and K.S.A. 65-1655; effective June 15, 1992; amended July 23, 1999; amended P-_____.)

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68-14-7a. Third-party logistics providers; minimum requirements for operation and maintenance of records. Each third-party logistics provider registrant shall meet the following minimum requirements for operation and the maintenance of records:

(a) Facilities. Each facility at which a third-party logistics provider is located shall meet the following requirements:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit or that are in immediate or sealed, secondary containers that have been opened or deemed unfit for distribution;

(4) be maintained in a clean and orderly condition;

(5) be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) be in a location separate from any pharmacy registered by the board or another state;

(7) be a commercial location and not a personal dwelling or residence; and

(8) have sufficient storage space to maintain records of all shipments pertaining to third-party logistics for at least five years.

(b) Security.

(1) Each facility used for third-party logistics shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

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(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs or devices are held shall be limited to authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription-only drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with manufacturer's recommendations to preserve the stability of these drugs and devices.

(1) If no storage requirements are established for a prescription-only drug or device, the drug or device may be held at room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these means shall be utilized to document proper storage of prescription-only drugs and devices at least once during each 24-hour period.

(3) The recordkeeping requirements in subsection (f) shall be followed for all stored prescription-only drugs and devices.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined to identify and

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to prevent the acceptance of prescription-only drugs or devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected to identify the prescription-only drugs or devices and to ensure that there is no delivery of prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (f) shall be followed for all incoming and outgoing prescription-only drugs or devices.

(e) Returned, damaged, and outdated prescription-only drugs or devices.

(1) Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-only drugs and devices until they are destroyed or returned to their supplier.

(2) Each prescription-only drug or device whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription-only drugs and devices until the drug or device is either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or

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purity, the registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (f) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs or devices.

(f) Recordkeeping.

(1) Each registrant shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs and devices. These records shall include the following information:

(A) The source of the drugs and devices, including the name and principal address of the seller or transferor, and the address of the location from which the drugs or devices were shipped;

(B) the identity and quantity of the drugs and devices received and either distributed or disposed of; and

(C) the dates of receipt and either distribution or other disposition of the drugs and devices.

(2) Inventories and records shall be made available for inspection and photocopying by an authorized representative of the board for five years following disposition of the prescription-only drugs or devices.

(3) The records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within

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two working days of a request by an authorized representative of the board.

(4) Each registrant shall post all current federal and state registrations in a conspicuous place.

(g) Written policies and procedures. Each registrant shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage, inventory, and distribution of prescription-only drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each registrant shall establish, maintain, and adhere to the following written policies and procedures:

(1) A procedure by which the oldest approved stock of a prescription-only drug or device is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate to meet the needs of the receiving facility;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs and devices. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) a procedure to ensure that the registrant prepares for, protects against, and handles any

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crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency; and

(4) a procedure to ensure that all outdated prescription-only drugs or devices are segregated from other drugs and devices and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription-only drugs or devices. Each registrant shall maintain this documentation for five years after disposition of each outdated prescription-only drug or device.

(h) Responsible persons. Each registrant shall establish and maintain a list of officers, directors, managers, and other persons in charge of prescription-only drug and device distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the board.

(i) Compliance with federal, state, and local law.

(1) Each registrant that deals in controlled substances shall register with the DEA.

(2) Each registrant shall permit the board's authorized personnel to enter and inspect the registrant's premises and delivery vehicles and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(3) Each registrant shall operate in accordance with the requirements of 21 U.S.C. 360eee, or any implementing regulation. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 65-1655a; effective P-_____.)

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68-14-7b. Outsourcing facilities; minimum requirements for operation and

maintenance of records. Each registrant who is the owner of an outsourcing facility shall meet the following minimum requirements for operation and the maintenance of records:

(a) Facilities. Each outsourcing facility shall meet the following requirements:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, or deemed unfit for distribution;

(4) have a quarantine area designated for holding products waiting for testing data before being released for distribution;

(5) be maintained in a clean and orderly condition;

(6) be free from infestation by insects, rodents, birds, or vermin of any kind;

(7) be a commercial location and not a personal dwelling or residence; and

(8) have sufficient storage space to maintain records of all shipments pertaining to outsourcing for at least five years.

(b) Security.

(1) Each facility used for outsourcing shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs and devices are held shall be limited to

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authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription-only drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with manufacturer's recommendations to preserve the stability of these drugs and devices.

(1) If no storage requirements are established for a prescription-only drug or device, the drug or device may be held at room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these means shall be utilized to document proper storage of prescription-only drugs and devices at least once during each 24-hour period.

(3) The recordkeeping requirements in subsection (f) shall be followed for all stored prescription-only drugs and devices.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined to identify and to prevent the acceptance of prescription-only drugs or devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage

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that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected to identify the prescription-only drugs or devices and to ensure that there is no delivery of prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (f) shall be followed for all incoming and outgoing prescription-only drugs and devices.

(e) Returned, damaged, and outdated prescription-only drugs and devices.

(1) Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-only drugs and devices until they are destroyed.

(2) Each prescription-only drug or device whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription-only drugs until the drug or device is either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, the registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its

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container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (f) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs and devices.

(f) Recordkeeping.

(1) Each registrant shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs and devices and any bulk active pharmaceutical ingredients used in compounding or manufacturing. These records shall include the following information:

(A) The source of the drugs and devices or the active pharmaceutical ingredients, including the name and principal address of the seller or transferor, the address of the location from which the drugs or devices were shipped, and the certificate of analysis if an active pharmaceutical ingredient was received;

(B) the identity and quantity of the drugs and devices or the active pharmaceutical ingredients received and either distributed or disposed of; and

(C) the date of receipt of the drugs and devices and the date of distribution or any other disposition of the drugs and devices.

(2) Records shall be made available for inspection and photocopying by an authorized representative of the board for five years following disposition of the prescription-only drugs or devices.

(3) The records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from

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the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized representative of the board.

(4) Each registrant shall post all current federal and state registrations in a conspicuous place.

(g) Written policies and procedures. Each registrant shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage, inventory, and distribution of prescription-only drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each registrant shall establish, maintain, and adhere to the following written policies and procedures:

(1) A procedure by which the oldest approved stock of a prescription-only drug or device is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate to meet the needs of the receiving facility;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs and devices including written notification to the board within 24 hours. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the registrant to remove defective or potentially defective drugs or devices from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

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(3) a procedure to ensure that the registrant prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) a procedure to ensure that all outdated prescription-only drugs or devices are segregated from other drugs or devices and destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription-only drug or device. This documentation shall be maintained for five years after disposition of the outdated prescription-only drug or device; and

(5) a procedure to ensure that prescription-only drugs and devices are sold only to registered entities with the authority to possess prescription-only drugs and devices in Kansas and to maintain documentation of this authority as part of the distribution record.

(h) Responsible persons. Each registrant shall establish and maintain a list of officers, directors, managers, pharmacists, pharmacy technicians, and other persons in charge of drug compounding, distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the board.

(i) Compliance with federal, state, and local law.

(1) Each registrant that deals in controlled substances shall register with the DEA.

(2) Each registrant shall permit the board's authorized personnel to enter and inspect the registrant's premises and delivery vehicles and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(3) Each registrant shall operate in accordance with section 503B of the federal food, drug, and cosmetic act, 21 U.S.C. 353b.

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(4) Each drug manufactured, prepared, propagated, compounded, or processed by an outsourcing facility without a registration issued by the board shall be deemed misbranded.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 65-1655b; effective

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